K041941
7/14/2004
1 of 2

SEP 13 2004

**510K Summary Of Safety and Effectiveness**
**Safe T Medical Devices Limited**
**July 14, 2004**

1. Sponsor Name

Safe T Medical Device Limited
PO Box 1, Portland House, Station Rd
Ballasalla, Isle of Man IM99 6AB, British Isles

Telephone: 00441514271271
Contact Individual: Peter Jeffrey

2. Device Name

Proprietary Name:
Safe T Retractable Blood Collection Device
Common/Usual Name:
Blood Collection Tube Holder

Panel: General Hospital
Classification Name: needle, hypodermic, single lumen
CFR Number: 880:5570
Product Code: FMI

3. Identification of Predicate or Legally Marketed Device

Retractable Technologies Vanish Point Tube Holder - K971763

4. Device Description

The Safe T Retractable Blood Collection Device is comprised of three components, a body, plunger and hub. The thread in the hub component matches that of all regular tube holders. The space within the holder is sufficient to fit all regular multi-sample needles after retraction. The device is supplied fully assembled, primed and ready for use, bulk packaged in polyethylene bags of 10 units. The device is non patient contacting and thus is sold non sterile.

5. Intended Use

The function of the Safe T Retractable Blood Collection Device is to provide a safe and reliable method for facilitating blood withdrawal from a patient into evacuated blood collection tubes without exposing the phlebotomist to an accidental needle stick injury. The Safe T Retractable Blood Collection Device

works like a conventional tube holder except for its ability to retract the contaminated needle inside of the tube holder immediately after blood collection.

6. Comparison of Technological Characteristics
The Safe T Retractable Blood Collection Device described in this submission is substantially equivalent to the predicate, the Retractable Technologies Vanish Point Tube Holder - K971763. Substantial equivalence of the Safe T Retractable Blood Collection Device is based on:

- Design similarities between the proposed device and the currently marketed device
- Technological Characteristics. The proposed Safe T Retractable Blood Collection Device and currently marketed Retractable Technologies Vanish Point Tube Holder - K971763 are similar in terms of materials of construction, performance characteristics, and basic design.

The intended use, technological characteristics of the materials and processes used in the application and safety characteristics of the Safe T Retractable Blood Collection Device support the concept of substantial equivalence. The Safe T Retractable Blood Collection Device has the same intended use and indication statement as the predicate device. The device has the same technological characteristics and operating design to that of its predicate. The Safe T Retractable Blood Collection Device uses the same operating principle as that of its predicate.

7 Performance Testing

Bench Testing and Simulated Use testing were performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Safe T Medical Devices Limited
C/O Ms. Debbie Iampietro
QRC Consulting
P.O. Box 1070
Conway, New Hampshire 03818-1070

Re: K041941
Trade/Device Name: Safe T Retractable Blood Collection Device
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 1, 2004
Received: September 3, 2004

Dear Ms. Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K041941

# Indications for Use

510(k) Number (if known): K041941

Device Name: **Safe T Retractable Blood Collection Device**

Indications For Use:

The function of the Safe T Retractable Blood Collection Device is to provide a safe and reliable method for facilitating blood withdrawal from a patient into evacuated blood collection tubes without exposing the phlebotomist to an accidental needle stick injury.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041941